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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/537,449 | 01/09/2006 | Bernd Schwenzler | 101215-189 | 1690 |
| 27387 7590 01/03/2008 NORRIS, MCLAUGHLIN & MARCUS, P.A. 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022 | | | EXAMINER SHIN, DANA H | |
| | | | ART UNIT 1635 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,449

Applicant(s)

SCHWENZER ET AL.

Examiner

Dana Shin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,10,11,13-16,19-21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 13-16,19-21 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,10,11 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2007 has been entered.

Status of Claims

Currently, claims 1-2, 4, 8, 10-11, 13-16, 19-21, 23-31 are pending. Claims 13-16, 19-21, and 23-27 have previously been withdrawn as being drawn to non-elected inventions. Accordingly, claims 1-2, 4, 8, 10-11, and 28-31 are currently under examination on the merits.

Response to Arguments

Applicant's arguments with respect to claims 1-2, 4, 8, and 10-11 have been considered but are moot in view of the new ground(s) of rejection. See below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, 10-11, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Cech et al. (US 6,093,809).

The claims are drawn to a polynucleotide directed towards a gene of a catalytic subunit of human telomerase, wherein the polynucleotide binds with SEQ ID NO:4 (target mRNA region of nucleotides 2206-2225, which is complementary to SEQ ID NO:10).

Note that the claimed polynucleotide does not confer any structural requirement (i.e., length limitation). All that is claimed and required of the polynucleotide is that it specifically binds with SEQ ID NO:4, which is part of the target mRNA sequence. Further, the polynucleotide is claimed to "contain" an oligonucleotide sequence of SEQ ID NO:10. The term "contain" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. In other words, the claimed polynucleotide is not limited to a 20-mer antisense oligonucleotide. As such, the claimed polynucleotide embraces any antisense polynucleotide that "contains" SEQ ID NO:10.

Cech et al. teach an antisense polynucleotide that specifically hybridizes to a gene of a catalytic subunit of human telomerase, wherein the polynucleotide is directed against SEQ ID NO:100 or variants thereof, wherein nucleotides 528-547 of SEQ ID NO:100 are identical to SEQ ID NO:4 of the instant application. They teach a composition comprising an antisense

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polynucleotide and a pharmaceutically acceptable carrier. See column 8, lines 54-63; column 9, lines 30-37; Figure 47. They teach that the antisense polynucleotide functions as a probe and therefore is bound to a solid support for Northern or Southern blot analysis. See columns 9, 16-17. Accordingly, all claim limitations are taught by Cech et al.

Claims 1-2, 4, 10-11, and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilian et al. (US 6,846,662 B1).

The claims are drawn to a polynucleotide directed towards a gene of a catalytic subunit of human telomerase, wherein the polynucleotide binds with SEQ ID NO:8 (target mRNA region of nucleotides 2331-2350) and contains SEQ ID NO:13 (complementary to SEQ ID NO:8).

Kilian et al. teach SEQ ID NO:45 and SEQ ID NO:47, whose nucleotides 2240-2259 are identical to SEQ ID NO:8 of the instant application. They teach antisense polynucleotides complementary to either SEQ ID NO:45 or SEQ ID NO:47, which contain SEQ ID NO:13 of the instant application and inhibit human telomerase activity. See column 23, lines 61-67; column 24, lines 1-17. They teach that the antisense polynucleotides can be used as probes in hybridization assays, which involve nitrocellulose membranes. See column 12, lines 19-37; column 24, lines 48-56. They teach a composition comprising an antisense polynucleotide and a pharmaceutically acceptable carrier. See column 29. Accordingly, all claim limitations are taught by Kilian et al.

Claims 1-2, 8, 10-11, and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuchiya et al. (US 6,608,188 B1).

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Claims 1-2, 10-11, and 28-31 are described above.

Claim 8 is drawn to the antisense polynucleotide modified by phosphothioate bonds.

Tsuchiya et al. teach a polynucleotide comprising an antisense strand of SEQ ID NO:1 or SEQ ID NO:9 or SEQ ID NO:11, whose nucleotides 621-640 correspond to the 20-mer sequence of SEQ ID NO:4 of the instant application and whose nucleotides 746-765 correspond to the 20-mer sequence of SEQ ID NO:8 of the instant application. They teach that the antisense polynucleotide inhibits human telomerase activity and can also be used as a probe kit that detects a cancer cell or as a therapeutic drug that treats cancer. See columns 3-4 and 9-11. They teach that the antisense polynucleotide comprises a phosphorothioate bond for increased nuclease resistance, cell permeability, and binding affinity. See columns 9-10. Accordingly, all claim limitations are taught by Tsuchiya et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

***/J. E. Angell/
Primary Examiner
Art Unit 1635***